

WHAT IS CLAIMED IS:

- 1 *Sub 17* 1. An assembly for crossing occlusive or stenotic material, the
2 assembly comprising:
3 a guidewire comprising an axial passage; and
4 a drive shaft rotatably and translatably extending through the axial passage
5 of the guidewire;
6 wherein the drive shaft comprises a distal tip that can be rotated and
7 advanced to create a path through the occlusive or stenotic material.
- 1 2. The assembly of claim 1 wherein the guidewire has a diameter
2 between approximately 0.009 inches and 0.035 inches.
- 1 3. The assembly of claim 1 wherein the assembly has a torqueability
2 and pushability to be advanced through a body lumen without the need of a separate
3 guidewire.
- 1 4. The assembly of claim 3 further comprising a detachable motor
2 coupled to a proximal end of the drive shaft that can impart a rotational movement to the
3 distal tip of the drive shaft.
- 1 5. The assembly of claim 1 wherein a proximal end of the drive shaft
2 can be manually rotated.
- 1 6. The assembly of claim 1 wherein the distal tip is flattened and
2 twisted.
- 1 7. The assembly of claim 1 wherein the distal tip has a width that is
2 larger than the width of the drive shaft.
- 1 8. The assembly of claim 1 wherein a distal end of the hollow
2 guidewire is steerable.
- 1 9. The assembly of claim 1 further comprising a housing coupled to
2 the proximal end of the hollow guidewire.

3 a hollow guidewire having a steerable distal end, a proximal end, and a
4 lumen therebetween;
5 a drive shaft movably disposed within the hollow guidewire, the drive
6 shaft having a longitudinal axis, a proximal end, and a distal tip portion;
7 a rotating mechanism coupled to the proximal end of the drive shaft; and
8 an actuator coupled to the drive shaft for controlling the axial movement of
9 the drive shaft;
10 wherein the activation of the actuator advances the rotatable drive shaft
11 from a retracted position to an extended position, wherein the rotating distal tip portion in
12 an extended position can create a path through the occlusion or stenosis.

1 21 The system of claim 20 wherein the distal tip portion is flattened
2 and twisted.

1 22. The system of claim 20 wherein the distal tip portion creates a path
2 forward of the hollow guidewire that is at least as large as the outer radius of the hollow
3 guidewire.

1 23. The system of claim 20 wherein the distal tip portion creates a path
2 forward of the hollow guidewire that is no larger than the outer radius of the hollow
3 guidewire.

1 24. The system of claim 20 wherein the distal tip portion comprises a
2 plurality of wires connected at their ends, a plurality of wires unconnected at their ends,
3 spiral with a blunt tip, or a loop.

1 25. The system of claim 20 wherein the hollow guidewire has the
2 pushability and torqueability to be advanced through a body lumen without the need of a
3 separate guidewire.

1 26. The system of claim 20 wherein the distal tip portion is deflectable,
2 sharpened, embedded, roughened, or coiled.

1 *Sub* 27. The system of claim 20 wherein the rotating mechanism and
2 actuator are coupled together such that the drive shaft is rotated and advanced
3 simultaneously.

1 28. The system of claim 20 wherein the rotating mechanism and
2 actuator are independently rotated and advanced.

1 29. The system of claim 20 wherein the rotating mechanism is
2 removably attached to the drive shaft.

1 30. The system of claim 20 wherein the lumen of the hollow guidewire
2 is configured to aspirate fluids and debris from or infuse fluids into the occlusion or
3 stenosis.

1 31. A system for crossing an occlusion or stenosis within a body
2 lumen, the system comprising:
3 an elongate member having a proximal end, a distal end, and an axial
4 passage extending to a distal tip at the distal end;
5 a drive shaft rotatably and translatably receivable in the axial passage of
6 the elongate member; and
7 a flattened and twisted distal tip attached to the drive shaft that can create a
8 path in front of the elongate member, wherein the drive shaft and distal tip are moveable
9 between an axially retracted configuration and an axially extended configuration.

1 32. The system of claim 31 wherein the distal tip in the axially
2 retracted configuration has a profile no larger than that of the distal tip

1 33. The system of claim 31 wherein the distal tip is sharpened.

1 34. The system of claim 31 wherein the distal tip comprises at least
2 two turns.

1 35. The system of claim 31 wherein the elongate member is a hollow
2 guidewire.

1 36. The system of claim 35 wherein the hollow guidewire has a
2 steerable tip.

1 37. The system of claim 35 wherein the hollow guidewire has a
2 diameter between approximately 0.009 inches and 0.035 inches.

1 38. The system of claim 31 further comprising a rotating mechanism
2 coupled to a proximal end of the drive shaft to facilitate rotation of the drive shaft.

1 39. The system of claim 38 wherein the mechanical rotating
2 mechanism is detachable from a proximal end of the drive shaft.

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2 40. A system for crossing an occlusion or stenosis within a body
3 lumen, the system comprising:
4 an elongate member having a proximal end, a distal end, and an axial
5 passage;

6 a drive shaft comprising a longitudinal axis rotatably and translatably
7 disposed in the axial passage of the elongate member, wherein a proximal portion of the
8 drive shaft is removably attached to a rotating mechanism and a distal tip is deflectable
9 off of the longitudinal axis;

10 wherein the rotating mechanism rotates the drive shaft so that a distal tip
11 of the drive shaft can be advanced beyond the distal end of the elongate member to create
a path that is large enough to pass the elongate member through the occlusion or stenosis.

1 41. The system of claim 40 wherein the elongate member has a
2 steerable tip.

1 42. The system of claim 40 wherein the elongate member has an outer
2 diameter between approximately 0.035 inches and 0.009 inches.

1 43. The system of claim 40 wherein the path created by the distal tip is
2 at least as large as the diameter of the distal end of the elongate member.

1 44. The system of claim 40 wherein the path created by the distal tip is
2 no larger than the diameter of the distal end of the elongate member.

1 45. The system of claim 40 wherein the drive shaft can extend up to 5
2 centimeters beyond the distal end of the elongate member.

1 46. The system of claim 40 wherein the drive shaft is movable between
2 a retracted position and an extended position, wherein the distal tip in the retracted
3 position can be completely disposed within the elongate member.

1 47. The system of claim 40 wherein the drive shaft is movable between
2 a retracted position and an extended position, wherein the distal tip in the retracted
3 position at least partially extends out of the distal end of the elongate member.

1 48. The system of claim 40 further comprising a support or access
2 system disposed over the elongate member, wherein the rotating mechanism is detached
3 from the drive shaft prior to positioning the support or access system over the elongate
4 member.

1 49. The system of claim 40 wherein the axial passage of the elongate
2 body is configured for infusion or aspiration of the body lumen.

1 50. A method of crossing an occlusion or stenosis within a body lumen
2 comprising:
3 positioning a hollow guidewire comprising a drive shaft into the body
4 lumen;
5 rotating the drive shaft within a lumen of the guidewire;
6 extending the drive shaft from a retracted configuration to an extended
7 configuration; and
8 advancing the distal portion of the drive shaft into the occlusion or
9 stenosis.

1 51. The method of claim 50 wherein the drive shaft is simultaneously
2 extended and rotated.

1 52. The method of claim 50 wherein the drive shaft is independently
2 extended and rotated.

1 53. The method of claim 50 wherein the drive shaft in the extended
2 configuration creates a path at least as large as the perimeter of the distal end of the
3 elongate member.

1 54. The method of claim 50 further comprising advancing the
2 guidewire through the body lumen without the use of a separate guidewire.

1 55. The method of claim 50 further comprising maintaining the
2 position of the guidewire during the advancing of the drive shaft.

1 56. The method of claim 50 further comprising moving a support
2 system through the body lumen.

1 57. The method of claim 56 wherein the support system is moved over
2 a guidewire, wherein the guidewire is removed from the support system prior to
3 positioning the hollow guidewire within the support system and body lumen.

1 58. The method of claim 56 wherein the support system is moved
2 through the body lumen over the hollow guidewire.

1 59. The method of claim 56 wherein a rotating mechanism is detached
2 from the drive shaft prior to moving the support system over the hollow guidewire.

1 60. The method of claim 56 further comprising infusing or aspirating
2 the body lumen through the support system.

1 61. The method of claim 56 further comprising maintaining the
2 position of the support system in the body lumen during the extending step.

1 62. The method of claim 56 further comprising using the support
2 system to perform a balloon angioplasty, stent placement, ultrasound, or an atherectomy.

1 63. The method of claim 50 further comprising infusing or aspirating
2 the body lumen through the hollow guidewire.

1 64. The method of claim 63 wherein the infusing or aspirating is
2 performed simultaneously with the creation of the path.

1 65. The method of claim 63 wherein infusing comprises delivering at
2 least one of a therapeutic material, rinsing material, a dye, and a diagnostic material
3 through the elongate member.

1 66. The method of claim 50 further comprising steering the distal end
2 of the elongate member.

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1 67. A kit comprising:
 2 a hollow guidewire having an axial passage;
 3 a rotatable drive shaft having a shaped distal tip, the rotatable wire being
 4 removably received within the passage of the hollow guidewire;
 5 instructions for use in passing through occlusions in a body lumen
 6 comprising rotating the inner wire within the steerable hollow guidewire and advancing
 7 the drive shaft into the occlusive material to create a path through the occlusive material;
 8 and
 9 a package adapted to contain the hollow guidewire, rotatable wire, and the
 10 instructions for use.

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1 68. The kit of claim 67 wherein rotation of the shaped distal tip creates
 2 a profile that is at least as large as the outer diameter of the hollow guidewire.

1 69. The kit of claim 67 wherein rotation of the shaped distal tip creates
 2 a profile that is no larger than the outer diameter of the hollow guidewire.

1 70. The kit of claim 67 wherein the hollow guidewire has an outer
 2 diameter between approximately 0.035 inches and 0.009 inches.

1 71. The kit of claim 67 wherein the shaped tip comprises a deflected
 2 tip, a sharpened tip, a coiled tip, or a roughened tip.

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3 72. The kit of claim 67 wherein the hollow guidewire has a steerable
 4 distal portion.

1 73. The kit of claim 67 further comprising a support or access system,
 2 wherein the support or access system is sized to removably receive the hollow guidewire
 3 and position a distal end of the hollow guidewire adjacent the occlusion.

1 74. The kit of claim 73 wherein the support or access system comprises
 2 an atherectomy catheter, support catheter, a balloon angioplasty catheter, a stenting
 3 catheter, infusion catheter, rotational catheter, extraction catheter, or a guiding catheter.

